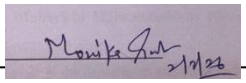
CERTIFICATE BY GUIDE

Certified that **DR. SAMTEN PALMULA BHUTIA,** is a Bonafede post-graduate student in the department of Oral and Maxillofacial Surgery in M. M. College of Dental Sciences and Research, Mullana, District Ambala, Haryana and is registered with M. M. (Deemed to be) University, Mullana, Ambala. He shall carry out genuine, scientific research work on his dissertation project on "Comparison in the efficacy of a novel dual-purpose surgical instrument for the enucleation vs Howarth Periosteal for enucleation of odontogenic pathologies" under our direct supervision



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DATE: 5/03/26

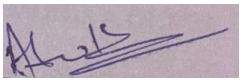
MAHARISHI MARKANDESHWAR COLLEGE OF DENTAL SCIENCES AND RESEARCH, MULLANA, AMBALA – 133203

HARYANA, INDIA

CERTIFICATE BY THE HEAD OF THE DEPARTMENT

This is to certify that **"Comparison in the efficacy of a novel dual-purpose surgical instrument for the enucleation vs Howarth Periosteal for enucleation of odontogenic pathologies"** will be a Bonafede dissertation work which will be done by **DR. SAMTEN PALMULA BHUTIA** in partial fulfilment of requirements for the degree of **Master of Dental Surgery** in the specialty of **Oral and Maxillofacial Surgery** at **Maharishi Markandeshwar (Deemed To Be) University**, **Mullana, Ambala**.

Facilities for carrying out this project exist in the department and the attached medical college hospital in the same campus.



DR. ATUL SHARMA
Professor and Head
Dept. Of Oral and Maxillofacial Surgery
M. M. College of Dental Sciences and Research
Mullana, Ambala

DATE: 5/03/26

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INTRODUCTION:

A wide spectrum of pathological lesions involves the mandible and maxilla, ranging from inflammatory, developmental cysts to benign and malignant tumours. These lesions may produce significant variation in the aesthetic, functional, and psychological morbidity of the affected patient. These lesions are often asymptomatic swellings but may also be associated with various clinical and pathological features like pain, infection, cortical expansion and tooth displacement.[1]

Surgical intervention is the most common management for pathologies due to variation in size, location, pathogenesis and potential for recurrence. A lot of discussions and disputes are going on for the treatment approaches for pathologies. Choosing the most effective modality should be the main goal of pathology management that has the least amount of morbidity and the lowest chance of recurrence.

The two main categories of management choices are radical resection and conservative treatment (enucleation of pathologies). Conservative treatment, such as marsupialisation or decompression, attempts to remove the pathology while maintaining the bony architecture as much as feasible. In oral and maxillofacial surgical practice, enucleation is the gold standard method for treating many odontogenic and non-odontogenic jaw cysts, where the cyst capsule is carefully separated from adjacent bone and soft tissues and removed entirely.[2]

The currently existing instruments have ergonomic challenges of taking longer operative time in all pathologies enucleation methods as ostectomy is done separately.

Due to these limitations of the existing instrument, a novel dual-purpose surgical instrument has been designed for easy removal of odontogenic pathologies from jaws along with ostectomy.

AIM AND OBJECTIVES

AIM:

To compare the feasibility, efficiency, and handling characteristics of a novel-designed dual-purpose (MonSa's surgical instrument) surgical instrument with Howarth's periosteal for enucleation of odontogenic pathologies from jaws along with ostectomy.

OBJECTIVES:

- To compare operative time for pathologies enucleation between the novel dual-purpose (MonSa's curette) surgical instrument and Howarth's periosteal.
- To compare the efficacy of the novel dual-purpose instrument in achieving complete enucleation of odontogenic pathologies along with ostectomy.
- To evaluate the ease of handling and ergonomics of the new instrument during pathology enucleation.
- To analyse surgeon satisfaction and usability feedback for the surgical instrument in oral and maxillofacial surgical practice.

REVIEW OF LITERATURE:

1. **Lucía Suárez-Pérez et al. (2025)** took sample which included five clinical trials with 231 cysts and 120 tumours in the experimental group. Participants had a mean age of 30.6 years, comprising 196 men and 141 women. Although conventional surgery was faster than piezosurgery, both techniques showed comparable results in terms of epithelial perforation, soft tissue injury, edema, postoperative infections and paraesthesia. The use of piezosurgery for removing benign odontogenic cysts and tumours in the jaws was found to offer modest intraoperative and postoperative benefits compared to conventional rotary techniques, except for longer surgical duration. It is associated with reduced bleeding during surgery and less postoperative pain, while other clinical outcomes remain comparable.[3]

2. **Masako Fujioka-Kobayashi et al. (2023)** used a custom-made surgical guide for the accurate enucleation of a nasopalatine cyst in the maxilla. 3D treatment planning was incorporated, where the patient's cone beam computerised tomography and scanned model data were assessed. Furthermore, it also had a sliding stopper for precisely indicating the inferior-most portion of the cyst. This case report suggested that the advancement in technology with the use of custom surgical guides can help with surgical precision and efficiency.[4]

3. **Ahmed A. Ragab et al (2022)** evaluated six cases of benign odontogenic cysts extending into the sinonasal region and demonstrated that tailored endoscopic approaches enable safe and complete enucleation. Depending on the direction of cyst expansion, surgeons used middle meatal antrostomy, minimal rhinotomy, or a sublabial approach, each providing adequate visualisation while preserving the Schneiderian membrane and adjacent structures. Their findings support endoscopic-assisted enucleation as a minimally invasive and effective option for managing sinonasal-invading cysts.[5]

4. **Hyuk Choi et al. (2021)** suggested that endoscope-assisted surgery has increasingly been adopted within oral and maxillofacial surgical procedures because it offers enhanced illumination, superior clarity, and magnified visualisation of the operative site. Early clinical reports highlight the feasibility of performing minimally invasive cyst enucleation using

endoscopic guidance. These preliminary experiences suggest that endoscope-assisted enucleation may provide functional and visual advantages that position it as a potentially superior alternative to traditional open surgical approaches.[6]

5. **Naveen Chhabra et al. (2018)** proposed a new technique of cyst enucleation in which they challenged the existing cyst enucleation technique by introducing a new modification to it, which ensured that there are lesser chances of perforating the cystic lining as well as ensured the complete removal of the cystic lining.[7]

6. **Yasmine A. Ibrahim et al. (2016)** had taken fourteen individuals in the Oral and Maxillofacial Surgery Department's outpatient clinic at Alexandria University's Faculty of Dentistry for the study. Clinical and radiological diagnoses were made for patients with radicular cysts in the jaw region. Seven patients received piezosurgery treatment, while the remaining seven patients were split into two groups at random and were given conventional surgical treatments. The two groups showed no signs of soft tissue injury or complicated manipulations, and the piezosurgery group saw reduced intraoperative bleeding.[8]

MATERIALS AND METHODS

STUDY DESIGN:

This study will be designed as a **prospective, comparative, clinical research** consisting of **30 samples**, divided into two groups, Group A and Group B. Group A will be using the novel dual-purpose (MonSa's curette) surgical instrument and in Group B, the Howarth's Periosteal. Clinical parameters and postoperative outcomes will be assessed and compared between the two groups.

The patent has already been applied for the surgical instrument named MonSa's curette with reference application number 493072-001. The copy of the application for the patent is attached here with (Annexure III).

STUDY SETTING:

This prospective clinical research will be carried out on 60 patients having radiological findings of odontogenic pathologies in the jaws at the Department of Oral and Maxillofacial Surgery at Maharishi Markandeshwar College of Dental Sciences and Research (MMCDSR), M.M. (Deemed to be University), Mullana, Ambala for complete excision of pathology along with ostectomy to prevent further recurrence. Once the Institutional Research Review Board and Institutional Ethical Committee will give their proper clearance, the study will be proceeded.

SELECTION CRITERIA:

INCLUSION CRITEIRA:

- Patients above 15 years of age.
- Pathology size should be more than 10 mm.
- Patients in ASA-I and ASA-II category.
- Patient should be cooperative and willing to participate in the study. (Informed Consent)
- Odontogenic pathologies of both the jaws.

EXCLUSION CRITERIA:

- Patients habituated to smoking, chewing tobacco products and drinking alcohol.
- Patients undergoing radiotherapy and chemotherapy.
- Patients with bone disorders like Ehlers–Danlos syndrome, osteogenesis imperfecta, etc.
- Patients with blood disorders, such as haemophilia, von Willebrand disease, thrombocytopenia and coagulation factor deficiencies.
- The pathologies causing extensive lingual cortical plate perforation.
- Soft tissue pathologies of the oral cavity.
- Patients with fibrous disorders and lesions like cherubism, fibrous dysplasia, ossifying fibroma, etc.

STUDY MATERIAL:

- A novel dual-purpose surgical instrument and Howarth's Periosteal'.

SAMPLE SIZE:

60 samples will be divided into two groups— Group A and Group B.

SELECTION OF PATIENTS:

Patients will be allotted by an envelope randomisation method. A total of 60 identical envelopes will be prepared, 30 will be labelled as Group A (Control Group – Howarth's Periosteal) and 30 will be labelled as Group B (Study Group – MonSa's Surgical instrument). All envelopes will be folded uniformly and placed in an opaque container.

For each patient, one envelope will be drawn at random. The group indicated on the envelope will determine Group A or Group B, ensuring proper randomisation and eliminating selection bias.

PARAMETERS TO BE STUDIED:

1. Ease of handling of the instrument (Likert scale)
2. Number of instrument exchanges
3. Time taken for complete pathology enucleation and ostectomy (Seconds)
4. Completeness of cystic lining removal (Intact/ Partial tear/ Multiple tears)
5. Surgeon's fatigue (Surgeon-Rated Surgical Difficulty Scale)
6. Bone volume. (Postoperative vs Postoperative)

ARMAMENTARIUM:

- Probe
- Mouth mirror
- Tweezers
- Disposable syringes (2ml) with needles (24 gauge)
- Lox 2%. (Lignocaine 2% with adrenaline 1:2,00,000)
- Lignocaine without adrenaline
- Surgical scalpel no.3
- Bard Parker blade no. 15
- Molt's #9 Periosteal elevators
- Howarth's periosteal elevators
- Adson's tissue holding forceps- Toothed and non-toothed
- Austin's tissue retractors
- Kilner's cheek retractors
- Bone cutting burs (Straight fissure burs and round burs no. 701/702/703)
- Bite block
- MonSa's Surgical instrument (experimental)
- Lucas curette
- Suction tips
- Suction tube
- Sterile gauze
- Sterile Cotton
- Bone rongeurs
- Bone files
- Needle holders
- Scissors
- Straight mosquito forceps
- Curved mosquito forceps
- 3-0 Silk reverse cutting suture
- 3-0 Vicryl reverse cutting suture
- Suture cutting scissors

PREOPERATIVE PROCEDURE:

Prior to the surgery, all patients will be examined clinically and asked for radiological investigation to rule out pathology and bone volume encompassing the pathology and advised for blood investigations.

SURGICAL PROCEDURE:

- All surgical procedures will be performed following standard surgical protocols.
- Lignocaine hydrochloride with 1:2,00,000 epinephrine will be administered to achieve adequate local anaesthesia or patient will be taken under GA depending upon severity of pathology.
- An appropriate surgical approach will be used for the removal of the pathology under aseptic conditions.
- Standard post-operative instructions will be given to all patients.
- Post-enucleation medications that will be prescribed:
    1. Capsule Amoxicillin 500 mg 3 times a day for 5 days.
    2. Tablet Metronidazole 400 mg 3 times a day for 5 days.
    3. Tablet Diclofenac sodium S.O.S.

POST OPERATIVE EVALUATION PARAMETERS

Both groups will be evaluated on the following clinical parameters:

- **EASE OF HANDLING OF THE NEW INSTRUMENT–**

  The ease of handling will be recorded for both the instruments using the Likert Scale in terms of the following:[9]

  1. Strongly disagree- The instrument is not at all easy to use.
  2. Disagree- The instrument is not easy to use.
  3. Undecided- The operator cannot decide if it's easy or not to use.
  4. Agree- The instrument is easy to use.
  5. Strongly agree- The instrument is very easy to use.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)

- **NUMBER OF INSTRUMENT EXCHANGES**

  The number of instruments exchanged during the surgical process will be counted in both groups.

- **TIME TAKEN FOR COMPLETE PATHOLOGY ENUCLEATION**

  Time taken for completion of enucleation of the pathology will be recorded by a Digital Stopwatch for both the groups.

- **COMPLETENESS OF CYSTIC LINING REMOVAL**

  The completeness of cystic lining removal will be noted at the time of surgery using an instrument for both groups in terms of the following:
  1. Intact- Complete enucleation of cyst sample with cystic lining in toto.
  2. Partial tear- Enucleation of cyst sample with partial tear of cystic lining.
  3. Multiple tears- Enucleation of cyst sample with multiple tears of cystic lining.

Intact	Partial tear	Multiple tears

- **SURGEON'S FATIGUE (Surgeon-Rated Surgical Difficulty Scale)**

The Surgeon's fatigue will be rated by using the most practical scale available- The Surgeon will Rate the Surgical Difficulty using the **Surgeon-Rated Surgical Difficulty Scale** in 5 points as follows: -

Very Easy	(1)
Easy	(2)
Moderate	(3)
Difficult	(4)
Very Difficult	(5)

- **VOLUME OF THE BONY DEFECT**

The amount of bone removed after enucleation of the pathology will be calculated by CBCT scan in terms of cubic mm (mm^3) pre-op to check bone volume and post op to see the amount of ostectomy that has been done with the instrument by subtracting the post op measurement from the pre op.

Pre-Operative (mm^3)	Post-Operative (mm^3)	Amount of bone volume removed (mm^3)
L*B*H=	l*b*h=	Preop-Postop=

CLINICAL SIGNIFICANCE

The clinical results of enucleation of odontogenic pathologies of the jaws in Oral and Maxillofacial surgery may be improved by the adoption of the novel innovative dual-purpose MonSa's surgical instrument. It may offer better handling, better access, better ergonomics and more accuracy in separating and removing the pathology along with required bone to be removed. This could minimize tissue damage, lessen surgeons' intraoperative fatigue and operating procedure time.

Conflict of interest: None

Sponsorship: Self

Copyright infringement: None

Risk of subjects: None

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ANNEXURE-I

DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY

CASE HISTORY

SR.NO: Date:

IDENTIFICATION DATA :

1. Name: _____
2. Age: _____
3. Gender: _____
4. OPD No.: _____
5. Address: _____
6. Mobile No: _____
7. Occupation: _____

CHIEF COMPLAINT(S):

_____

_____

HISTORY OF PRESENT ILLNESS:

_____

_

MEDICAL HISTORY

_____

_____

_____

ALLERGIES

_____

ORAL HABITS

_____

EXAMINATION

EXTRA ORAL EXAMINATION

INTRA ORAL EXAMINATION

DIAGNOSIS

_____

_____

_____

TREATMENT PLAN

TREATMENT DONE

PROFORMA

GROUP A- Using the novel dual purpose (MonSa's) surgical instrument

- **EASE OF HANDLING OF NEW INSTRUMENT**

  LIKERT SCALE

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)

- **NUMBER OF INSTRUMENT EXCHANGES**

Names of instruments used	No. of instruments used

- **TIME TAKEN FOR COMPLETE PATHOLOGY ENUCLEATION AND OSTECTOMY** (from exposure to complete ostectomy)

Time taken for complete pathology enucleation and ostectomy (Seconds)

- **COMPLETENESS OF CYSTIC LINING REMOVAL**

Intact	Partial tear	Multiple tears
[ ]	[ ]	[ ]

- **SURGEON'S FATIGUE (Surgeon-Rated Surgical Difficulty Scale)**

Very Easy	(1)
Easy	(2)
Moderate	(3)
Difficult	(4)
Very Difficult	(5)

- **VOLUME OF THE BONY DEFECT**

Pre-Operative (mm^3)	Post-Operative (mm^3)	Amount of bone volume removed (mm^3)
L*B*H=	l*b*h=	Preop-Postop=

GROUP B- Using the Howarth's Periosteal

- **EASE OF HANDLING**

  LIKERT SCALE

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)

- **NUMBER OF INSTRUMENT EXCHANGES**

Names of instruments used	No. of instruments used

- **TIME TAKEN FOR COMPLETE PATHOLOGY ENUCLEATION AND OSTECTOMY**(from exposure to complete ostectomy)

Time taken for complete pathology enucleation and ostectomy (Seconds)

- **COMPLETENESS OF CYSTIC LINING REMOVAL**

Intact	Partial tear	Multiple tears
[ ]	[ ]	[ ]

- **SURGEON'S FATIGUE (Surgeon-Rated Surgical Difficulty Scale)**

Very Easy	(1)
Easy	(2)
Moderate	(3)
Difficult	(4)
Very Difficult	(5)

- **VOLUME OF THE BONY DEFECT**

Pre-Operative (mm^3)	Post-Operative (mm^3)	Amount of bone volume removed (mm^3)
L*B*H=	l*b*h=	Preop-Postop=

MAHARISHI MARKANDESHWAR (DEEMED TO BE) UNIVERSITY, MULLANA (AMBALA)

INFORMED CONSENT DOCUMENT (ICD)

Patient / Participant information sheet

INFORMATION FOR PARTICIPANTS OF THE STUDY

Title of the project: **"Comparison in the efficacy of a novel dual-purpose surgical instrument for the enucleation vs Howarth's Periosteal for enucleation of odontogenic pathologies"**

1. **Name of the investigator/guide-** DR. SAMTEN PALMULA BHUTIA

   (PRINCIPAL INVESTIGATOR)

   GUIDE- DR. MONIKA GUPTA

Purpose of this project/study- To compare the feasibility, efficiency, and handling characteristics of a novel-designed dual-purpose (MonSa's) surgical instrument with Howarth's Periosteal for enucleation of odontogenic pathologies from jaws along with ostectomy.

Procedure/methods of the study- Patients reporting to the OPD, Department of OMFS having the radiological findings of odontogenic pathologies in the jaws fulfilling the inclusion and exclusion criteria.

2. **Expected duration of the subject participation-** In this prospective study, the assessment will be performed as quick, short- spanned in order to avoid patient's discomfort. Patient will be followed up postoperative for the evaluation of bone volume.
3. **The benefits to be expected from the research to the participant or to others**- to prevent further recurrence of pathology.
4. **Any risks expected from the study to the participant**- There is no potential risk to the participant related to the study.
5. **Maintenance of confidentiality of records**- The data collected will be kept confidential and your personal identity will not be revealed in public but, the observed data may be published in scientific journals.
6. **Provision of free treatment for research related injury**- NONE

7. **Compensation for participating in the study**- NONE

8. **Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death**- NONE

9. **Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled**- The participant has all the freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant **would otherwise be entitled**.

Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned- No

10. **Address and mobile number of the Principal Investigator (PI) and Co- PI, if any**:

Dr Samten Palmula Bhutia, PG Resident, Department of Oral and Maxillofacial Surgery, MMCDSR Maharishi Markandeshwar (Deemed to Be University), Mullana, Ambala, 133207. Mob no.- 9970009487

_____ Signature of the investigator: _____

Signature of the participant

_____

Place and Date

CBR Detail:

Sr. No.	Ref. No./Application No.	App. Number	Amount Paid	C.B.R. No.	Form Name	Remarks
1	493072-001		1000	205169	FORM 1	Surgical Curette

TransactionID	Payment Mode	Challan Identification Number	Amount Paid	Head of A/C No
D-0000139052	Online Bank Transfer	2702260055169	1000.00	1475001020000001

Total Amount : ₹ 1000

Amount in Words: Rupees One Thousand Only

Received from Neha Goyal the sum of ₹ 1000 on account of Payment of fee for above mentioned Application/Forms.

* This is a computer generated receipt, hecnce no signature required.

Synopsis_1725708_Samten Palmula Bhutia

ORIGINALITY REPORT

5%	%	5%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Atul Sharma, Dinesh Kumar, Deepika Patidar, Mamit Kumar, Dinesh Chand Patidar, Punita Garg. "Evaluation of Ocular Injuries in Maxillofacial Trauma:A Prospective Study", Dental Journal of Advance Studies, 2023 Publication	1%
2	Masako Fujioka-Kobayashi, Naoki Miyasaka, Ayako Miyasaka, Masateru Koyanagi, Ryo Inada, Takahiro Miyasaka, Takafumi Satomi. "A Custom-Made Surgical Guide for Accurate Enucleation of Nasopalatine Duct Cysts: A Technical Note and Case Report", Case Reports in Dentistry, 2023 Publication	1%
3	J.-P Latham, Ping Lu. "Development of an assessment system for the blastability of rock masses", International Journal of Rock Mechanics and Mining Sciences, 1999 Publication	1%
4	Anthony Kalloo, Jonathan Buscaglia. "Complicated Cases in GI", CRC Press, 2024 Publication	<1%
5	Kocyigit, Ismail Doruk, Fethi Atil, Yunus Emre Alp, Umut Tekin, and Hakan H. Tuz. "Piezosurgery Versus Conventional Surgery in Radicular Cyst Enucleation :", Journal of Craniofacial Surgery, 2012. Publication	<1%